73. The ELP fusion protein of claim 72, in a composition comprising a solvent medium in which the ELP fusion protein exhibits an inverse phase transition upon a predetermined change of composition condition.

B2 SWK CS

74. The ELP fusion protein of claim 73, wherein said composition further comprises a cleavage agent effective to cleave the cleavage site of the ELP fusion protein to yield the protein of interest and the ELP as cleavage products.

75. The ELP fusion protein of claim 74, wherein said cleavage agent is a proteolytic agent effective to proteolytically cleave the cleavage site of the ELP fusion protein.

Response to Restriction Requirement, and Introduction of New Claims

In response to the restriction requirement imposed by the Examiner in respect of the claims 1-65 originally filed in the application, applicant hereby elects, WITH TRAVERSE, the Group I claims 1-34, and requests that the Examiner reconsider the restriction requirement with respect to all identified claims groups, and particularly with respect to the Group I and Group II claims (protein and DNA encoding same), and with respect to Group I and Group IV claims (protein and method of purification of same, wherein all claims reside in class 530, and the search effort would not be unduly burdensome).

New claims 66-75 have been introduced herein, for addition to the Group I claims.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. 35 U.S.C. § 121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without independence and distinctness, a restriction requirement is unauthorized.

In the instant case, the claims are not independent - the Examiner has expressly stated in the Office Action that the Group II claims encode protein of the Group I claims. Further, the Group III claim is directed to optimizing the size of an ELP expression tag, and applicant's fusion protein claims of Group I recite an ELP component - these claims therefore are interrelated, and not independent of one another. Further, Groups I and IV as noted above reside in the same USPTO class, and therefore have been categorically determined to the USPTO to be broadly interrelated to one another.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA, predecessor to the CAFC, has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. *In re Kuehl,* 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Office held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the

public's interest, the Office is not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

In view of the foregoing discussion, reconsideration for the withdrawal of the restriction requirement is courteously requested.

Please charge the fee for addition of added claims 66-75, in the amount of $132, together with any other fee or charge properly payable for this response, to Deposit Account 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,

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APPENDIX A

Version of Claim 9 with Markings to Show Changes Made

9. (amended) The fusion protein of claim 1 wherein the phase transition is mediated by one or more means selected from the group comprising:

(f) changing temperature;

(g) changing pH;

(h) addition of [organic] solutes and/or solvents,

(i) side-chain ionization or chemical modification; and

(j) changing pressure.